K093992

TERUMO

Section 5
510(k) Summary

MAY 19 2010

TERUMO

Submitter Information:

This submission was prepared in December 2009 by:

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This submission was prepared for:
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Terumo Luer Lock Adapters	Adapter, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass	Adapters

Predicate Device(s):

The Terumo Luer Lock Adapters are substantially equivalent to following predicate Luer Lock Adapters (510(k): K992906) with respect to intended use, design, technology/principles of operation, materials and performance:

Corresponding New Terumo Luer Lock Adapter Part #	Terumo Luer Lock Predicate Part #	Predicate Description
0001-11302	0001-11301	1/8" Female Luer Adapter
0001-12302	0001-12301	1/8" Male Luer Adapter
0001-21302	0001-21301	3/16" Female Luer Adapter
0001-22302	0001-22301	3/16" Male Luer Adapter
0001-31302	0001-31012	Threaded Female Luer Adapter
0001-32302	0001-22301	3/16" Male Luer Adapter
0001-71303	0001-71302	Female Luer Lock Adapter
0001-72303	0001-72302	Male Luer Lock Adapter

The differences between the devices do not raise any new issues of safety or effectiveness.

Device Indications/Intended Uses:

The adapters are single use, disposable components, intended to be used to interconnect tubing and other devices during cardiopulmonary bypass procedures. The device may be used in procedures lasting up to 6 hours in duration.

Device Description:

The adapters are intended to be used to interconnect tubing and other devices during cardiopulmonary bypass procedures. For use up to six hours.

One end of the luer lock adapter has a male or female luer lock connection which may be connected to any opposite luer fitting within the tubing pack. The opposite side of the luer lock adapter has a tubing connection point which is barbed for the 1/8", 3/16" and ¼" male and female adapters. The Pressure line luer adapters have an internal slip fit connection point for tubing.

The tubing connection points are generally bonded to tubing with the appropriate inner diameter (1/8", 3/16", ¼") or pressure line tubing using cyclohexanone. In some cases, a tie-band is attached to the outside of the tubing connection to the luer lock adapter.

The luer fitting may be pre-connected to an opposite luer fitting within the cardiopulmonary bypass circuit by Terumo Cardiovascular Systems. The luer fitting may be connected by the end-user to either another opposite luer fitting within the cardiopulmonary bypass circuit or to an external luer fitting.

The luer lock adapters provide a leak proof connection point between components and various lines within the circuit, with the ability for a user to easily disconnect and re-connect the adapters as needed to any other opposite standard luer fitting. The luer lock adapters can be disconnected and re-connected by hand.

Performance Testing:

The following tests were conducted in order to demonstrate the Terumo Luer Lock Adapters are substantially equivalent to the predicate devices.

- Dimensional Stability
- Pre-connection
- Connection Strength
- Circulation Test
- Pressure Test

Additional Safety Information:

Sterilization conditions for the Terumo Luer Lock Adapters are validated to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.

Terumo maintains biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Terumo Luer Lock Adapters are *substantially equivalent* to the predicate Luer Lock Adapters. It is further concluded that any recognized differences noted during the assessments do not raise any new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL - 8 2010

Terumo Cardiovascular Systems Corporation
c/o Ms. Eileen Dorsey
Regulatory Affairs Specialist
125 Blue Ball Rd.
Elkton, MD 21921

Re: K093992
Terumo Luer Lock Adapter
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: April 2, 2010
Received: April 5, 2010

Dear Ms. Dorsey:

This letter corrects our substantially equivalent letter of May 19, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TERUMO

Section 4
Indications for Use

510(k) Number (if known): ~~Unknown at time of submission~~ → K093992

Device Name: Terumo Luer Lock Adapters

Indications for Use:
The Terumo Luer Lock Adapters are single use, disposable components, intended to be used to interconnect tubing and other devices during cardiopulmonary bypass procedures. The devices may be used in procedures lasting up to 6 hours in duration.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D)

OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vanhuss

(Division Sign-Off)
Division of Cardiovascular Devices

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